



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 14 2003

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Michael Campbell  
Senior Manager, Regulatory Affairs/Quality Assurance  
Olympus America, Inc.  
3131 West Royal Lane  
Irving, TX 75063-3104

Re: k031380  
Trade/Device Name: Olympus HbA1c Reagent Test System (Reagent, Calibrator & Control, Hemoglobin Denaturant)  
Regulation Number: 21 CFR 864.7470  
Regulation Name: Glycosylated Hemoglobin Assays  
Regulatory Class: Class II  
Product Code: LCP, JIS, JJX  
Dated: August 4, 2003  
Received: September 9, 2003

Dear Mr. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

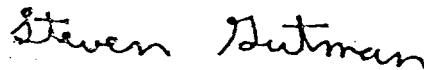
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K031380

Device Name: Olympus HbA1c Reagent Test System (Reagent, Calibrator & Control,  
Hemoglobin Denaturant)

**Indications for Use:**

In vitro diagnostic method for the quantitative measurement of Hemoglobin A1c in human whole blood on the Olympus system analyzers.

Measurements obtained through this method can be used for monitoring the long-term care of people with diabetes.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use ☒ OR Over-The-Counter Use ☐  
(per 21 CFR 801.109) (Optional Format 1-2-96)

*Alan Corzales*  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K031380